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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Yehuda Sharf

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EXAMINER

SZMAL, BRIAN SCOTT

ART UNIT

PAPER NUMBER

3736

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/599,693	Applicant(s) SHARF ET AL.	
	Examiner Brian Szmaj	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-42 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 October 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: ____. |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :5/2/08; 7/21/08; 9/16/09; 2/1/10.

Drawings

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the memory as claimed in Claim 14, must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 2, 13, 15, 16, 19, 20, 22, 25, 29 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claim 2 discloses “said output signal comprises a signal selectively suppressed responsive to said measured posture”. The current specification fails to explicitly disclose why or how to “suppress” a signal in response to a measured posture. Claim 13 discloses “said output signal is generated is a posture change is not maintained”. The current specification fails to disclose the generation of an output signal in response to not maintaining a specific posture. At best, the current specification only supports monitoring the posture of the woman to determine if the posture change was or is being maintained. Claims 15, 16, 25 and 29 disclose the extraction of a physiological parameter from the posture sensor signal, and using a single sensor to acquire a posture parameter and a physiological parameter. The current specification fails to disclose any extraction of a physiological signal from a posture signal, and using a single sensor for measuring both a posture of the woman and a physiological parameter. The current specification only discloses the use of two separate sensors for acquiring the signals, and the current specification fails to disclose how a posture signal can be used to generate a physiological signal. Claim 19 discloses “said output signal comprises a recommendation to a caregiver regarding posture”. The

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current specification fails to support providing an output to a caregiver. At best, the current specification provides support for providing an output for recommending a particular posture based on the measured parameters. Claim 20 discloses "said posture sensor is housed together with at least a part of said at least one sensor". The current specification discloses housing both the posture sensor with the physiological sensor, not housing the posture sensor with a part of the physiological sensor. Claim 22 discloses "discarding a physiological measurement responsive to a posture measurement". The current specification fails to disclose how or why a physiological measurement is "discarded" due to a posture measurement.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 14, 20 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 20 discloses "said posture sensor is housed together with at least part of said at least one sensor". It is unclear to the Examiner how a posture sensor can be housed with "at least part of" a physiological sensor. One of ordinary skill in the art would not be able to house a part of a sensor with the posture sensor, since the physiological sensor can only be housed with the posture sensor or not housed with the posture sensor.

Claim 22 discloses "gel-like" material. It is unclear to the Examiner what constitutes a "gel-like" material. Material are either gels, solids or liquids.

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6. Claim 14 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements, such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: how the claimed memory of Claim 14 interacts with the claimed elements of Claim 1. In particular, the elements of Claims 1 and 14 lack a structural relationship with respect to how the correspondence between the posture and the physiological parameter stored in memory interact with the circuitry for generating an output signal based on the measurement of the posture and the physiological parameter.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1, 3-5, 7-9, 15, 16, 20, 21, 24, 27 and 42 are rejected under 35 U.S.C. 102(b) as being anticipated by Mault (2002/0028995 A1).

Mault discloses a means for remote pregnancy monitoring and further discloses a monitor including at least one sensor operative to measure a physiological parameter associated with labor; a posture sensor for generating a signal indicative of the posture of the mother; circuitry which generates an output signal dependent upon the measurement of the sensor and the posture measurement; the circuitry is operative to

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modify the output signal responsive to the posture signal; the circuitry is operative to generate a signal indicative of a change in the physiological parameter responsive to a change in posture; the physiological parameter comprises a geometry of a cervix; the physiological parameter comprises a fetal physiological parameter; the fetal physiological parameter comprises a fetal heart rate; the physiological parameter comprises a maternal physiological parameter; extracting a physiological parameter from the sensor; the physiological parameter comprises breathing; the posture sensor is housed with the at least one sensor; measuring a postural parameter of the patient; measuring a physiological parameter associated with labor; generating a signal responsive to both of the measurements; tracking a change in the physiological parameter responsive to the posture measurement; monitoring the compliance of the patient with a posture change; mounting the element in an adhesive mount; applying a coupling material suitable for ultrasonic coupling to the element; and stripping a covering from the mount, thereby exposing an adhesive layer of the mount and removing excess material. See Paragraphs 0019, 0037, 0038, 0040-0043, 0048 and 0050.

9. Claims 34-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Hon et al (5,070,888).

Hon et al disclose a uterine contraction monitoring device and further disclose an elastic adhesive ring adapted to adhere to a human skin; a selectively locking mount attached to the ring; a housing adapted to receive a sensor and selectively lockable to the mount, and configured to provide mechanical contact of at least one part thereof to

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the skin to which the ring adheres; the locking mount is a snap mounting; and the mount interlocks with at least one aperture in the ring. See Figures 1-3 and 9B.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mault (2002/0028995 A1) as applied to claim 1 above, and further in view of Chance (2007/0167704 A1).

Mault, as discussed above, disclose a means for monitoring parameters pertaining to pregnancy, but fails to disclose the physiological parameter comprises a fetal head position relative to the birth canal of the mother.

Chance discloses a transabdominal examination, monitoring and imaging of tissue and further discloses determining the fetal head position relative to the birth canal of the mother. See Paragraph 0079.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the means of Mault to include the measurement of the fetal head position, as per the teachings of Chance, since it would provide a means of predicting the onset of labor, and provide a means of determining if the fetus is in a breach birth position.

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12. Claims 10, 11, 26 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mault (2002/0028995 A1) as applied to claims 1 and 21 above, and further in view of Daum et al (2005/0283197 A1).

Mault, as discussed above, disclose a means for monitoring parameters pertaining to pregnancy including physiological parameters of the mother or fetus and monitoring the posture of the mother and outputting a result based on both the physiological parameter and the posture, but fails to explicitly disclose the physiological parameter is changed by a change in posture; the measurement by the sensor is changed by a change in posture; monitoring an effect of posture change on the physiological parameter; and determining a change in posture based on a measured change in the at least one physiological parameter.

Daum et al disclose a means for monitoring hypotension and further disclose physiological parameters are affected by a person's posture. See Paragraphs 0008-0009.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to recognize physiological parameters are affected by the posture of a person, since the posture of the person affects the internal organs, and blood pressure of the person.

13. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mault (2002/0028995 A1) as applied to claim 1 above, and further in view of Sliwa et al (6,039,701).

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Mault, as discussed above, disclose a means for monitoring parameters pertaining to pregnancy with a plurality of external sensors, but fails to disclose the sensor comprises at least one internal probe and at least one external probe serving as a reference thereto.

Sliwa et al disclose a means of monitoring cervical diameter and further disclose at least one internal probe. See Figure 2A.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the means of Mault to include the use of at least one internal probe, as per the teachings of Sliwa et al, since it would provide a means of accurately monitoring the cervical dilation and therefore monitoring the progress of labor.

14. Claims 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mault (2002/0028995 A1) as applied to claim 1 above, and further in view of Sackner et al (6,551,252 B2).

Mault, as discussed above, disclose a means for monitoring parameters pertaining to pregnancy, but fails to disclose the posture sensor comprises an acceleration sensor; and the posture sensor is calibrated to be aligned to one or more maternal body axes.

Sackner et al disclose a means for monitoring physiological signs and further disclose the posture sensor comprises an acceleration sensor; and calibrating the sensors. See Column 11, lines 53-65; and Column 16, lines 40-44.

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the means of Mault to include the use of an acceleration sensor and calibrating the sensor, as per the teachings of Sackner et al, since it is well known in the art to utilize accelerometers for measuring the tilt or posture of a person, while accurately correlating the sensors to specific locations on the body.

15. Claims 23 and 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mault (2002/0028995 A1) as applied to claim 21 above, and further in view of Hatlestsad (7,400,928 B2).

Mault, as discussed above, disclose a means for monitoring parameters pertaining to pregnancy, but fails to disclose correcting a measurement based on a posture measurement; applying a correction value to the physiological parameter; updating the correction value when a posture change is detected; and assuming that the physiological parameter does not change over a period of time of the occurrence of the posture change.

Hatlestsad et al disclose a means for detecting context when addressing a medical condition of a patient and further disclose correcting a measurement based on a posture measurement; applying a correction value to the physiological parameter; updating the correction value when a posture change is detected; and assuming that the physiological parameter does not change over a period of time of the occurrence of the posture change. See Abstract.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the means of Mault to correct a physiological parameter,

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as per the teachings of Hatlestsad et al, since it would provide a means of calculating the physiological parameter while taking into account extraneous factors that affect the physiological measurement.

16. Claim 28 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mault (2002/0028995 A1) as applied to claim 21 above, and further in view of Heruth et al (2005/0216064 A1).

Mault, as discussed above, disclose a means for monitoring parameters pertaining to pregnancy, but fails to disclose determining a side on which the person is lying.

Heruth et al disclose a means for selecting therapy parameter sets and further disclose a means for determining which side a person is lying on. See Paragraph 0061.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the means of Mault to determine the position of the person, as per the teachings of Heruth et al, since would provide a means of allowing the processor to determine if the person is lying on the correct side to prevent stress on the fetus.

17. Claims 37-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hon et al (5,070,888) as applied to claim 34 above, and further in view of Mault (2002/0028995 A1).

Hon et al, as discussed above, disclose a means for attaching a sensor to a skin of a pregnant woman, but fail to disclose the sensor is an ultrasonic transducer adapted to ultrasonically communicate through a center of the ring and wherein the mechanical

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contact is suitable for ultrasonic transmission therethrough; the sensor includes an inclination (posture) sensor; circuitry for RF communication; a power source in the housing; and circuitry for digitizing and processing ultrasound signals.

Mault, as discussed above, disclose the use of attached ultrasonic transducers to measure physiological parameters of the mother and the fetus, as well as the posture of the mother, and further disclose the sensor is an ultrasonic transducer adapted to ultrasonically communicate through a center of the ring and wherein the mechanical contact is suitable for ultrasonic transmission therethrough; the sensor includes an inclination (posture) sensor; circuitry for RF communication; a power source in the housing; and circuitry for digitizing and processing ultrasound signals. See Paragraphs 0019, 0021, 0037, 0038, 0040-0043, 0048 and 0050.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the sensor assembly of Hon et al to include the use of an ultrasonic transducer disposed within the center of the sensor assembly, as per the teachings of Mault, since it would provide an alternative means of attaching the sensor assembly to the pregnant woman.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmaj whose telephone number is (571)272-4733. The examiner can normally be reached on Monday-Friday, with second Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Brian Szmal/
Examiner, Art Unit 3736